AF/37 S2

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on May 6, 2003

Carolyn Beason-Wright

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**AF**

**EXPEDITED PROCEDURE**

#10
5-13-03



**PATENT**

**CASE NO.: 8627/092 (PA-5239-RFB)**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re Application of: | ) | |
| | ) | |
| Matthew M. Graf, et al. | ) | Examiner: Hook, James F. |
| | ) | |
| Serial No.: 09/810,377 | ) | Group Art Unit: 3752 |
| | ) | |
| Filed: March 16, 2001 | ) | |
| | ) | |
| For: INTRODUCER SHEATH | ) | |

**RESPONSE UNDER 37 C.F.R. § 1.116**

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This paper is responsive to the final Office Action mailed March 26, 2003. In the Office Action, a final rejection was issued for all claims 1, 2, 4-6 and 10-16. Applicants respectfully request re-examination and reconsideration of the claim rejections in view of the remarks provided hereinbelow.

The present application is directed to an introducer sheath that includes a short distal tip section that is substantially more radiopaque than the remainder of the sheath. As claimed in claim 1, the broadest claim in the patent application, the distal tip section of the introducer sheath is made of fluorinated ethylene propylene (FEP), and contains between about 20% and 75% by weight of a specified radiopaque material.

It is desirable for an introducer sheath to be formed of a polymeric material that has sufficient radial rigidity to remain open upon removal of the dilator, but that is also sufficiently flexible to permit manipulation without kinking under conditions of normal use. Prior to the present invention, it was known to provide such an introducer sheath with a separate flexible soft distal tip portion that was bonded to the distal end of a sheath formed of a harder material. Such flexible soft distal tip portions were utilized to minimize vessel wall trauma that might otherwise occur if harder, less flexible distal tip materials were used. These known soft distal tip portions have generally been made of copolymers that can be substantially loaded with radiopaque materials such as tungsten or barium, while the rest of the introducer adjacent to the distal tip portion contains substantially less radiopaque material. Copolymers, however, have a higher coefficient of friction than is desirable. It is desirable to utilize a material having a low coefficient of friction, so that catheters and other interventional devices can pass through the sheath with a minimum of resistance. It is also desirable that the low friction material be amenable to high loadings of radiopaque material, and yet maintain good flexibility and kink resistance. Furthermore, the low friction material should be of a type that provides a reliable bond with the main body of the sheath material. Surprisingly, it has been found that the use of FEP as a distal tip material meets these criteria.

The formation of a reliable bond at the interface between the short, highly radiopaque copolymer distal tip and the dissimilar sheath material has been problematic. The bond zone between the tip and the sheath material realizes very high stresses because it is at or very near the area that gets the most bending forces. Relatively large differences in material properties across a short bond zone further concentrate the stresses in the bond zone, making the bond susceptible to failure. Since the sheath is usually placed in an artery, the separation of a short tip segment from the remainder of the sheath would result in a dangerous embolus free floating in the arterial

system, that would eventually lodge somewhere and occlude blood flow to tissue. Thus, to increase the safety of such a device, the present inventors provided a highly radiopaque low friction material (FEP) for the tip that mimicked the physical properties of the sheath, and that forms a reliable bond with the sheath material.

By forming the distal tip of FEP, the inventors were able to capitalize on an extrudable material that, surprisingly, could also be highly loaded with radiopaque material. The bonding of this material to the sheath material insures a good molecular mix of molten materials. The highly loaded tip material does not readily flow into and mix with the sheath material during the bonding process because it has such a high percentage of filler material. Frequently, the interface between prior art materials at the bond site is a "cold" bond or adhesive connection. Although such a connection may initially appear to provide a strong weld or bond, it is in fact much weaker than desired. The present inventors have addressed this bonding problem by forming the tip of FEP.

When the distal tip is formed of FEP, a particularly reliable bond can be formed. An example of such a bond with male and female mating taper is shown in Fig. 2. When a tip and sheath are first put together, prior to heating and bonding, they do not fit as shown in Fig. 2. This interface is designed so that when the material in the bond zone melts during bonding, the sheath and tip move together causing a shearing of the molten material at the interface. This shearing action forces the highly loaded tip material to actually blend or mix with the sheath material. The overall result is a true molecular mixing or weld between the two materials. The highly radiopaque tip becomes an integral part of the sheath and radiographically distinguishes the exact distal end of the sheath.

The tip member of the catheter described in the primary Parker reference was made of a polyether block amide material, with nylon being a named example. The Parker reference fails to teach or even suggest the use of FEP as a material for the tip. Although the secondary Jansen reference discloses the use of FEP in a catheter, the FEP is used as a lubricious inner liner material (Col. 9, lines 35-43), or as a segment of lesser flexibility (**218** in Fig. 2F), and not as a distal tip material. This segment of lesser flexibility is then coupled with more flexible distal

segments 212, 214, 216 that are formed of other compositions. Neither the Parker nor the Jansen reference discloses a distal tip portion having high loadings of radiopaque markers. Furthermore, neither reference discusses the difficulty in attaining high loadings with FEP, nor the problem of improving the bonding and radiopacity of certain segments relative to other segments.

In the final Office Action the Examiner also discussed the Coneys reference (U.S. Patent No. 4,657,024). According to the Examiner, this reference disclosed high loadings (70-80%) of FEP. However, a closer reading of Coneys indicates that the radiopaque layer described therein actually comprises only between about 12 and 25% of the total material making up the tube (Col. 3, lines 59-64). Contrary to the present invention, the radiopaque portion of the Coneys structure is "completely embedded within and surrounded by plastic material", which is also FEP. See, e.g., Col. 3, lines 25-28. There is no indication that the radiopaque layer of Coneys could function as a distal tip without the presence of the additional surrounding FEP in which the radiopaque layer is embedded.

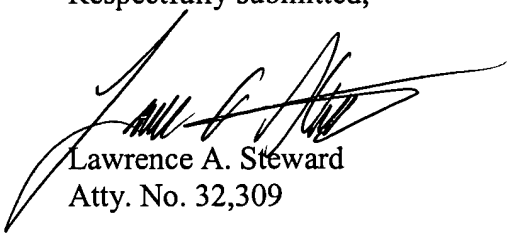
In the present claims, the radiopaque material comprises between about 20 and 75% of the total material making up the distal tip (with the exception of claims 2, 10 and 14, wherein the percentage of radiopaque material is between about 50 and 55%). Unlike Coneys, the distal tip of the present introducer sheath is not surrounded by or embedded in anything. When a desirable feature of a distal tip for an introducer sheath is to maintain a profile as narrow as possible, the use of an "embedded and surrounded" layer such as taught in Coneys would be counterproductive. This difference may be due to the fact that the Coneys disclosure is directed to "medical-surgical" catheters in general, and is not directly concerned with introducer sheaths.

Even though there are additional distinguishing characteristics between the Coneys disclosure and the present invention that could be noted, Applicants respectfully point out that Coneys has not even been cited in any of the present rejections of record. Rather, the Examiner has only discussed this reference in his "Response to Arguments" portion of the Office Action. If the Examiner intends to rely on this reference as a basis for rejection of the claims, Applicants respectfully request that a new, non-final action be issued. At that time, Applicants could

address this reference at greater length, and provide additional arguments that the cited combination of references (whatever it ultimately turns out to be) is not appropriate.

Based upon the foregoing remarks, Applicants respectfully submits that claims 1, 2, 4-6 and 10-16 are in condition for allowance. Accordingly, Applicants respectfully request the issuance of a Notice of Allowance. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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